



Guidance for Drug Take-Back Programs

Drug Take-Back Programs for Household Pharmaceutical Waste

Pharmaceutical waste, such as prescription medication, over-the-counter medication, and controlled substances, can be a source of concern for many reasons. If managed poorly, this type of waste can harm human health and the environment. It can also increase the chance for accidental overdose and drug abuse. In an effort to prevent these problems, many communities in Kentucky offer special disposal programs. Drug take-back programs, for example, provide a location where citizens can safely drop off unused or expired medications. The collected items are then taken to a facility where they are properly destroyed and disposed. Since these programs are closely monitored by local, state, and federal agencies, they are the safest method and best option for disposal.

Environmental Guidance for Kentucky

*Kentucky's Division of Compliance Assistance (DCA) developed this document to provide guidance to organizers of drug take-back programs. Organizers of these programs typically include law enforcement agencies, pharmacies, health clinics, and treatment centers. In order to implement a drug take-back program, these entities must register with the U.S. Drug Enforcement Administration as **authorized collectors**. Authorized collectors not only plan and carry out the goals of the program, they are responsible for complying with environmental regulations. This publication highlights the regulations that apply to the disposal of drugs that are collected from these programs.*

Hazardous Waste Pharmaceuticals

A portion of household pharmaceuticals that are collected through drug take-back programs include **hazardous waste pharmaceuticals (HWPs)**. HWPs are regulated by the Environmental Protection Agency (EPA) because they have the potential to pollute the environment. Some HWPs may also be controlled substances that are regulated by the Drug Enforcement Administration (DEA). Controlled substances are regulated because of the potential for their abuse. With respect to take-back programs that accept household pharmaceutical waste, including HWPs and controlled substances, EPA focuses on disposal methods that require incineration and emissions control. DEA, on the other hand, focuses on collection and handling and requires that the drugs to be permanently destroyed.

EPA's Final Rule

EPA's definition of hazardous waste is "waste with properties that make it dangerous or capable of having a harmful effect on human health or the environment". Hazardous waste pharmaceuticals cannot be disposed of by common means like typical household garbage. Therefore, waste that is categorized as hazardous must be disposed of according to certain rules. HWPs, for example, must be separated and incinerated. This rule, along with other rules for handling HWPs is published in the ***EPA Final Rule for the Management Standards for Hazardous Waste Pharmaceuticals***. Details for EPA's Final Rule can be viewed at the following link: <https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075>.

DEA's Final Rule

As noted earlier, DEA regulates pharmaceutical controlled substances. DEA's rules apply to the collection, transfer, destruction, return, and recall of controlled substances. As part of the ***DEA Final Rule for Disposal of Controlled Substances***, authorized collectors are allowed to accept and dispose of controlled substances. They must, however, use a disposal method that meets the non-retrievable standard of destruction. DEA's Final Rule includes the non-retrievable standard along with other rules for managing controlled substances. DEA's Rule can be viewed at the following link: https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf.

Waste Management

Organizers and Types of Drug Take-Back Programs

Drug take-back programs include several options for disposing household pharmaceutical waste, including controlled substances. These options include take-back events, mail-back programs, and collection receptacles. Most of these programs are run by law enforcement agencies. Under DEA rules, law enforcement agencies can maintain collection containers at their locations. The rules also allow law enforcement to partner with other entities to hold take-back events and assist with collection programs. In addition to law enforcement, DEA now allows certain registrants to oversee mail-back programs. These registrants, or authorized collectors, include distributors, reverse distributors, narcotic treatment programs, hospitals, clinics, and retail pharmacies. In short, the purpose of DEA regulations is to provide safe collection and to expand disposal options.

EPA's role with respect to organizing drug take-back programs has less to do with collection and more to do with disposal. EPA's overall goal is to keep dangerous drugs out of waterways. In order to do this, EPA recommends that household pharmaceuticals collected through take-back programs be incinerated in a permitted hazardous waste combustor. If a hazardous waste combustor is not feasible, then the items must be made inert and sent to a permitted large or small municipal waste combustor. Although there are no municipal waste combustors in Kentucky, the use of out-of-state, permitted waste combustors is allowed. The disposal methods required by EPA are intended to accommodate a waste stream that is likely mixed with both hazardous and non-hazardous pharmaceutical waste.

Compliance Guidelines for Authorized Collectors

Authorized collectors must plan carefully in order to comply with both DEA and EPA regulations. Understanding these regulations, however, can be a challenging task. Adding to the challenge is the fact that there are more than one set of regulatory requirements. To help with compliance, a summary for both DEA and EPA requirements is provided below. Although the summaries offer a concise list of requirements for both agencies, it is advisable to contact both DEA and EPA to make certain that the specifics of the rules are followed and that standards are met.

Summary of Compliance Requirements per DEA's Final Rule

- ◆ Any authorized collector registered with DEA can maintain **collection receptacles** for unwanted or expired drugs, including controlled substances.
- ◆ Any authorized collector registered with DEA can maintain **mail-back programs** for unwanted or expired drugs, including controlled substances.
- ◆ Only law enforcement agencies have the authority to carry out **collection events** for unwanted or expired drugs, including controlled substances. Although any person can assist with these events, only law enforcement agencies have the authority to conduct them. The National Prescription Drug Take-Back Day, for example, is an event arranged through law enforcement agencies.
- ◆ Authorized collectors may accept the following items for disposal:
 - * household pharmaceutical waste (prescriptions and over-the-counter)
 - * controlled substances (only from those who legally possess a controlled substance)
 - * commingled controlled substances along with non-controlled substances from households
- ◆ Authorized collectors are prohibited from accepting the following items for disposal:
 - * illicit drugs and controlled substances that were illegally obtained
 - * hazardous waste pharmaceuticals generated by healthcare facilities, commercial business, or industry (*items are only accepted from households*).



Compliance Guidelines for Authorized Collectors

Summary of Compliance Requirements per DEA's Final Rule (cont.)

- ◆ Although not specified in regulation, DEA strongly discourages authorized collectors from accepting the following items for safety reasons and to avoid other requirements:
 - * sharps, needles, syringes, asthma inhalers, compressed cylinders, unused auto-injectors, mercury-containing thermometers, and iodine-containing medications.
- ◆ Authorized collectors are not required to register as a hazardous waste generator with federal or state environmental agencies.
- ◆ Authorized collectors must ensure that the pharmaceuticals collected at take-back programs are non-retrievable. Non-retrievable means that the substance is unavailable and unusable for all practical purposes. To become non-retrievable, the method of disposal must permanently change the substance's physical or chemical make-up through irreversible means. DEA's irretrievable standard for disposal includes incineration and fuel blending, both thermal based treated processes.
- ◆ Authorized collectors who transport household pharmaceutical waste collected at drug take-back programs must obtain a Special Permit, SP 20255, from the U.S. Department of Transportation (DOT). The permit exempts authorized collectors from having to ship the contents as a hazardous material.

Summary of Compliance Requirements per EPA's Final Rule

- ◆ In collaboration with DEA, EPA requires all discarded pharmaceuticals collected at take-back programs be destroyed and/or disposed at a permitted facility. Any incinerators or combustors used for destruction and disposal must have been issued an air quality permit. The permitted unit, however, must also have the technology to meet DEA's non-retrievable standards. For this reason, authorized collectors should always contact both DEA and EPA (or KY DEP) when selecting a particular method, such as incineration or fuel blending, and a particular type of combustor for destruction and disposal.

Examples of facilities that have the ability to effectively incinerate and destroy pharmaceutical waste include:

- * *hazardous waste, hospital/medical/infectious waste, or sewer sludge incinerators*
 - * *coal-fired boilers, cement kilns, lightweight aggregate kilns, or lime kilns*
- ◆ Per EPA's Final Rule, there are five types of combustors that are approved to destroy pharmaceutical waste collected in take-back programs.

The types of combustors approved by EPA include:

- * *permitted large municipal waste combustors*
- * *permitted small municipal waste combustors*
- * *permitted hospital, medical and infectious waste incinerators*
- * *permitted commercial and industrial solid waste Incinerators*
- * *permitted hazardous waste combustors*



Compliance Guidelines for Authorized Collectors

Summary of Compliance Requirements per EPA's Final Rule (cont.)

- ◆ As an alternative to using a permitted facility with the ability to effectively destroy and dispose of the pharmaceutical waste, authorized collectors also have the option to purchase and operate a portable device that uses thermal treatment technologies. Portable devices such as these must be permitted and must meet the specifications for effectively destroying the materials. *Note: An air quality permit is required for portable units owned and operated by a government agency if it used to destroy household pharmaceutical waste collected from a take-back program. An air quality permit is not required if the unit is owned or operated by a government agency and it is used to destroy only illegal drugs that have been confiscated as contraband.*
- ◆ Authorized collectors are prohibited from using the following methods of disposal for household pharmaceutical waste collected at drug take-back events:
 - * cremation (crematoriums do not meet the guidelines for thermal treatment).
 - * “sewering” or dumping collected pharmaceuticals down the drain.
 - * “landfilling” or disposing collected pharmaceuticals in landfills prior to being rendered inert.

Best Management Practices

Note: These points are in addition to the regulatory requirements of federal agencies as well as the Kentucky Department for Environmental Protection (KY DEP).

Setting Up the Program:

- ◆ Contact DEA and register as an authorized collector for drug take-back programs.
- ◆ Contact EPA or KY DEP to ensure compliance with disposal regulations.
- ◆ Contact DOT to ensure compliance when transporting pharmaceutical waste.

Maintaining Collection Sites:

- ◆ Provide oversight of collection containers (may include electronic surveillance).
- ◆ Maintain a secure collection container to prevent theft and any release of pharmaceutical waste.
- ◆ Use a plastic liner in collection containers in order to prevent leaks and ensure easier transport.
- ◆ Provide signage at drop-off locations to ensure that only household pharmaceuticals are accepted.
- ◆ Provide signage regarding the items accepted for disposal and the items prohibited.
- ◆ Provide signage to inform users that medications should not be mixed with any other hazardous waste or solid waste stream, including confiscated or illicit drugs.

Complying with Disposal:

- ◆ Use facilities that are properly permitted and have adequate technologies.
- ◆ Maintain records to show compliance with state and federal requirements.

Recordkeeping should include:

- * amounts of pharmaceuticals collected
- * name of collection provider (if applicable)
- * name and permit number for disposal facility
- * date, location, and witness of disposal
- * method of destruction and/or disposal



Useful Links and Resources

- ♦ U.S. Drug Enforcement Administration: National Drug Take-Back Day
<https://takebackday.dea.gov/>
- ♦ U.S. Drug Enforcement Administration: Drug Take-Back Programs and Registration
https://www.deadiversion.usdoj.gov/drug_disposal/
- ♦ U.S. Drug Enforcement Administration: Drug Take-Back Locations
<https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1>
- ♦ U.S. Department of Transportation: Special Permit 20255 for Transporting Drug Take-Back
<https://www.phmsa.dot.gov/news/phmsa-special-permits-key-resource-national-prescription-drug-take-back-program>

KY DEP Contacts

Division of Compliance Assistance

300 Sower Blvd.
Frankfort, KY 40601
502-782-6189 (DCA help desk)
www.dca.ky.gov
E-mail: envhelp@ky.gov

Division for Air Quality

300 Sower Blvd.
Frankfort, KY 40601
502-564-3999 (phone)
www.air.ky.gov

Division of Waste Management

300 Sower Blvd.
Frankfort, KY 40601
502-564-6716 (phone)
www.waste.ky.gov

DEA Contacts

DEA Office – Lexington, KY
859-977-6100

DEA Office – London, KY
606-682-4500

DEA Office – Louisville, KY
502-582-5908

DEA Office – Madisonville, KY
270-821-6899

Disclaimer: The Division of Compliance Assistance helps small businesses, local governments, and the general public comply with state environmental regulations. This document is intended solely as guidance and is not a substitute for reading and understanding Kentucky's statutes and regulations governing the applicability and issuance of environmental permits.



Kentucky Division of Compliance Assistance

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